REMARKS

As a preliminary matter, attention is directed to the Petition for Extension of Time of four months submitted herewith.

A current claim summary is presented as an addendum to this response, starting on its own separate sheet.

Claim 49 has been amended by incorporating claim 50 therein. By the amendment, claim 49 now states that substantially all of the drug in the solid dispersion is amorphous. Applicants have also made amendments to improve form by inserting "and" in two places.

Claim 50 has been canceled.

Applicants note that the amendments herein have been made without waiver or prejudice to their right to file one or more continuation applications directed to deleted subject matter.

Claims 49, 52, 55-57 and 59-62 were rejected under 35 USC 103(a) as being unpatentable over Curatolo, WO 95/30422 in view of Kigoshi, US 6,254,889. The examiner appeared to reason that Curatolo discloses bi-layer osmotic tablets comprising a drug layer and an expandable hydrogel layer, plus other excipients and components, as noted in the Office Action, such as osmagents. The examiner acknowledged that Curatolo does not disclose the claimed dispersion polymer in the core.

Applicants note that the Examiner did not reject claim 50 over the combination of Curatolo and Kigoshi. The non-rejection of claim 50 is presumably an indication that claim 50 would be allowable if written in independent form. Accordingly, Applicants have now incorporated claim 50 into claim 49 and respectfully submit that claim 49 is patentable over Curatolo and Kigoshi. Applicants respectfully request confirmation by the Examiner of the patentability of Applicants' amended claims in the next Office Action, hopefully a Notice of Allowance.

In addition to amending claim 49 in a way that Applicants respectfully submit obviates the patentability rejection over Curatolo and Kigoshi, Applicants also respectfully submit that the rejection based on Curatolo and Kigoshi is not legally tenable because it is based on hindsight. Applicants note their invention relates to simultaneously providing higher dissolved drug concentrations for a low-solubility drug while also providing controlled release, and that accomplishing both of these ends constituted a thorny problem since controlled release of a sparingly aqueous soluble drug can decreases bioavailability. Curatolo and Kigoshi, in and of themselves, provide

no teaching, suggestion or motivation for their combination, it being further noted that the Supreme Court has recently counseled against the bias of hindsight:

> A fact finder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post facto* reasoning. See *Graham*, 383 U.S 1. at 36, 86 S.Ct. 684 (warning against a 'temptation to read into the prior art the teachings of the invention in issue' and instructing courts to 'guard against slipping into the use of hindsight' '(quoting *Monroe Auto Equipment Co. v. Heckethorn Mfg. & Supply Co.*,.

KSR Int'l v. Teleflex Inc., 127 S. Ct. 1727 (2007), at 1742-43. There is no basis provided in either Curatolo or Kigoshi that would lead one to implement a solid amorphous dispersion in which the drug is substantially completely amorphous in an osmotic controlled release form, however. Curatolo simply demonstrates that certain osmotic controlled release devices are known, but is unrelated to making solid amorphous dispersions. Kigoshi is unrelated to controlled release. Only Applicants, in their own specification, supplied the incentive for implementing a solid amorphous dispersion in a particular type of osmotic controlled release device. It is well accepted, however, that Applicants own disclosure can not be used as a reference against them, in effect using the invention taught against its teacher. *W.L. Gore & Associates v. Garlock, Inc.*, 721 F.2d. 1540, 1553 (Fed. Cir. 1983). There is no teaching, suggestion or motivation that would warrant combining the references in the manner indicated in the Office Action.

Parenthetically, Applicants note that the teaching-suggestion-motivation test (TSM) remains the primary test of obviousness even after the KSR ruling. This has been recently emphasized by the Federal Circuit:

> As this court has explained, however, a flexible TSM test remains the primary guarantor against a non-statutory hindsight analysis such as occurred in this case. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007) ("[A]s the Supreme Court suggests, a flexible approach to the TSM test prevents hindsight and focuses on evidence before the time of invention."). The TSM test, flexibly applied, merely assures that the obviousness test proceeds on the basis of evidence—teachings, suggestions (a tellingly broad term), or motivations (an equally broad term)—that arise before the time of invention as the statute requires. As KSR requires, those teachings, suggestions, or motivations need not always be written references but may be found within the knowledge and creativity of ordinarily skilled artisans.

Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc., __ F. 3d __ (Fed. Cir. March 31, 2008).

It is accordingly respectfully requested, particularly in view of the amendments and the comments noted above, that the rejection under 35 USC 103(a) over Curatolo in view of Kigoshi be withdrawn.

Claims 49-52, 55-57, and 59-62 were rejected under 35 USC 103(a) over Curatolo in view of Kerc, WO 96/36318. The rejection is traversed for reasons analogous to those presented above, and as further explained below.

Kerc discloses a three-phase pharmaceutical form that is not an osmotic dosage form. Kerc puts his active ingredient plus other components including PVP and a surfactant (i.e., his first phase) into a second phase comprising "sustained release agents" such as a cellulose ether and a mixture of mono, di, and triglycerides and then adds a "poorly soluble or gastro-resistant film coating" as a third phase. One of ordinary skill in the art would recognize the Kerc dosage form as a coated matrix delivery system. The polymers employed by Kerc are enteric, as indicated by Kerc in his disclosure. Because Kerc's coatings are enteric and dissolve in the higher pH environment of the lower GI tract, they are not "non-dissolving and non-eroding during release of said drug", as required by Applicants. None of the polymers required by Applicants for their solid amorphous dispersion are disclosed in Kerc as dispersion polymers.

Applicants respectfully note that Kerc's disclosure is thus related to an altogether different controlled release dosage from the osmotic dosage forms disclosed in Curatolo. As a broad summary of Applicants' position, Applicants respectfully submit one of ordinary skill would not find it obvious to combine (1) a reference that discloses osmotic dosage forms (Curatolo) with (2) a single element (a dispersion) from a reference that discloses a different dosage form (Kerc), especially considering that (3) the dispersion element selected from Kerc is distinct from the dispersion required by Applicants' claims because, *inter alia*, (4) the "stabilizing" polymers disclosed in Kerc differ from the dispersion polymers required by Applicants.

Applicants accordingly submit their invention is not obvious over Curatolo and Kerc because the only basis for combining the two references is hindsight, Applicants' previous discussion relating to Curatolo v. Kigoshi being equally applicable to Curatolo v. Kerc. Kerc discloses a matrix delivery (i.e., non-osmotic) dosage form. Curatolo discloses certain known osmotic dosage forms, but discloses nothing about osmotic dosage forms containing a solid dispersion in which substantially all of the drug is amorphous. Considering Curatolo, Kerc, and Applicants' specification, the only disclosure relating to employing Applicants' solid amorphous dispersion in an osmotic controlled release device is Applicants' specification. No basis has been provided for one of ordinary skill in the art to modify the teachings of either reference, or that would support combining an osmotic dosage form like that disclosed in Curatolo with a completely different dosage form like the one disclosed in Kerc. There is no basis for selecting the single element of a dispersion from Kerc from among all of the elements

Kerc discloses, particularly when the stabilizing polymers disclosed by Kerc are distinct from the dispersion polymers required by Applicants. Only Applicants have disclosed such an embodiment, but again Applicants' specification may not be used as prior art against them.

It is accordingly respectfully submitted that the rejection of Applicants claims over Curatolo and Kerc should be withdrawn.

In view of the foregoing comments and amendments, this case is believed to be in condition for allowance, and a Notice of Allowance is courteously solicited.

Respectfully submitted,

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James T. Jones
Attorney for Applicant(s)
Reg. No. 30,561

Pfizer Inc.
Patent Department, Box 8260-1611
Eastern Point Road
Groton, CT 06340
(860) 441-4903